K043102

JAN 2 1 2005

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the Multi-use Compression Screw.

Submitted By:	Wright Medical Technology, Inc.
Date:	November 4, 2004
Contact Person:	Wesley L. Reed Regulatory Affairs Specialist
Proprietary Name:	**Multi-Use Compression Screw**
Common Name:	Bone Fixation Screw
Classification Name and Reference:	21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener – Class II
Device Product Code and Panel Code:	21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener – Class II

DEVICE INFORMATION

A. INTENDED USE

The Multi-Use Compression Screw is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

-Mono or Bi-Cortical osteotomies in the foot or hand
-Distal or Proximal metatarsal or metacarpal osteotomies
-Weil osteotomy
-Fusion of the first metatarsophalangeal joint and interphalangeal joint
-Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.)
-Akin type osteotomy
-Arthrodesis base first metatarsal cuneiform joint to reposition and stabilize metatarsus varus primus
-Calcaneus/ cuboid arthrodesis
-talar/ navicular arthrodesis

B. DEVICE DESCRIPTION

The design features of the Multi-Use Compression Screw are summarized below:

- Manufactured from Stainless Steel
- Offered in two diameters: 3.0mm and 4.3mm
- Offered in lengths ranging from 10mm-60mm
- Offered in two thread lengths: short and long
- Self drilling and self tapping features on both distal and proximal threads
- Proximal threaded head is fully recessed into bone to allow for a zero profile once fully inserted

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The design features, material, and indications for use of the Multi-use Compression Screw are substantially equivalent to the previously cleared Newdeal BOLD® Compression Screw and the Newdeal I.CO.S.® Screw. This was confirmed by testing conforming to ASTM 543-02. The safety and effectiveness of the Multi-use Compression Screw is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 1 2005

Mr. Wesley L. Reed
Regulatory Affairs Specialist
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K043102
Trade/Device Name: Multi-Use Compression Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: November 5, 2004
Received: November 9, 2004

Dear Mr. Reed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Multi-Use Compression Screw

Indications For Use:

The Multi-Use Compression Screw is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

-Mono or Bi-Cortical osteotomies in the foot or hand
-Distal or Proximal metatarsal or metacarpal osteotomies
-Weil osteotomy
-Fusion of the first metatarsophalangeal joint and interphalangeal joint
-Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.)
-Akin type osteotomy
-Arthrodesis base first metatarsal cuneiform joint to reposition and stabilize metatarsus varus primus
-Calcaneus/ cuboid arthrodesis
-talar/ navicular arthrodesis

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043102